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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/888,079	06/22/2001	Signe Erickson Varner	55821 (71699)	6574

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EXAMINER

KONTOS, LINA R

ART UNIT PAPER NUMBER

3763

DATE MAILED: 02/11/2004

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/888,079

Applicant(s)

VARNER ET AL.

Examiner

Lina Kontos

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 November 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 23-73 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 23-73 is/are rejected.
- 7) ☒ Claim(s) 26 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

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Claim Objections

1.

Claim 26 is objected to because of the following informalities: the claim currently reads that it is dependent on claim 23 and "any one of claims 23 through 25". For the purposes of this examination, Examiner has interpreted the claim as if it were depending solely on claim 23.

Appropriate correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

2.

Claims 23-30,32,33-40,42-44,47-52,54,55,58-65,67-69,72,73 are rejected under 35 U.S.C. 102(e) as being anticipated by Paques et al.

Paques et al. discloses a method for treating an eye with a device comprising a piercing member (4) with an outer diameter less than 25 gage [0053] allowing the puncture location to self-seal and having a flexible plastic tube therein [0087] to administer a therapeutic substance to the eye. The device is used to treat conditions such as vascular occlusion [0039] by advancing

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the device transconjunctively and piercing the sclera of the eye and delivering a therapeutic agent subretinally.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3.

Claims 31,45,46,56,57,70,71 are rejected under 35 U.S.C. 103(a) as being unpatentable over Paques et al. in view of del Cerro et al.

Paques et al., as described above, teaches a device for subretinal delivery of a therapeutic agent wherein the device has an outer piercing member and an inner cannula, but fails to teach withdrawal of fluid from the eye.

Del Cerro et al. teaches a device comprising a tip for penetrating the subretinal region of the eye to deliver a therapeutic agent or withdraw fluid from the eye (column 4, line 31).

It would have been obvious to one skilled in the art at the time of the invention to withdraw fluid from the eye in order to reduce the pressure in the eye, as well as to deliver therapeutic fluid to treat the disease or injury, both actions possible with the syringe connected to the device of Paques.

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4.

Claims 41,53,66 are rejected under 35 U.S.C. 103(a) as being unpatentable over Paques et al. in view of Bowman et al.

Paques et al., as described above, teaches a device for subretinal delivery of a therapeutic agent wherein the device has an outer piercing member and an inner cannula, but fails to teach the delivery of steroids.

Bowman et al., teaches a device for delivery of a therapeutic agent such as steroids, genetic material, or pharmaceuticals to the eye.

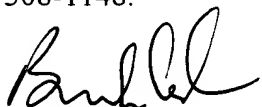
It would have been obvious to one skilled in the art at the time of the invention to deliver agents such as steroids to the eye depending on the needs of the patient.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lina Kontos whose telephone number is (703) 306-4207. The examiner can normally be reached on M-F 8:30-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on (703) 308-3552. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9302.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1148.

LRK


BRIAN L. CASLER
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